Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: WATER

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Report Date:04/29/2009

Study Summary

Laboratory Name	Study Number	Study Start Date	Length of Study in Days	Number of Animals Total and (#/Cage)	Number Surviving and (Mean Life Span)	Maximum Mean Weekly Body Weight	Chemical
				Ma	ale		
Battelle Columbus Laboratory Battelle Columbus Laboratory Battelle Columbus Laboratory	058812307 052000506 059501106	10/04/01 02/10/04 08/09/01	728 730 728	50 (1) 50 (1) 50 (1)	39(698) 32(691) 40(702)	52.9 51.1 52.3	Formamide Ginseng 5-(Hydroxymethyl)-2-furfural
				Fer	nale		
Battelle Columbus Laboratory Battelle Columbus Laboratory Battelle Columbus Laboratory	058812307 052000506 059501106	10/03/01 02/09/04 08/08/01	727 729 727	50 (5) 50 (5) 50 (5)	38(692) 38(711) 39(694)	64.7 63.9 64.4	Formamide Ginseng 5-(Hydroxymethyl)-2-furfural

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Tumor Incidence for Selected Control Animal Groups

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Report Date:04/29/2009

Contract/Lab: All Laboratories Species: MICE

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

Route: GAVAGE Vehicle: WATER

			Male				Female	
#All Organs: Benign Tumors		31/50 (62%)	38/50 (76%)	42/50 (84%)		17/50 (34%)	33/50 (66%)	26/50 (52%)
Overall Incidence	Total	111/150 (74%)	Mean 74%	SD 11.14%	Total	76/150 (50.67%)	Mean 50.67%	SD 16.04%
#All Organs: Malignant Tumors		20/50 /500/	20/50 /50%	20/50 /529/)		00/50 /500/	45/50 (200()	40/50 (200()
Overall Incidence	Total	28/50 (56%) 80/150 (53.33%)	26/50 (52%) Mean 53.33%	26/50 (52%) SD 2.31%	Total	26/50 (52%) 57/150 (38%)	15/50 (30%) Mean 38%	16/50 (32%) SD 12.17%
#All Organs: Malignant and Benign To	umors	44/EO (920/)	46/50 (029/)	40/50 (099/)		26/50 /720/\	42/50 (949/)	24/50 (699/)
Overall Incidence	Total	41/50 (82%) 136/150 (90.67%)	46/50 (92%) Mean 90.67%	49/50 (98%) SD 8.08%	Total	36/50 (72%) 112/150 (74.67%)	42/50 (84%) Mean 74.67%	34/50 (68%) SD 8.33%
#All Organs: Hemangioma		2/50 (4%)	1/50 (2%)	0/50 (0%)		0/50 (0%)	1/50 (2%)	2/50 (4%)
Overall Incidence	Total	3/150 (2%)	Mean 2%	SD 2%	Total	3/150 (2%)	Mean 2%	SD 2%
#All Organs: Hemangiosarcoma		3/50 (6%)	4/50 (8%)	2/50 (4%)		2/50 (4%)	0/50 (0%)	E/EO (409/)
Overall Incidence	Total	9/150 (6%)	4/50 (8%) Mean 6%	2/50 (4%) SD 2%	Total	7/150 (4.67%)	Mean 4.67%	5/50 (10%) SD 5.03%
#All Organs: Hemangiosarcoma or He	emangioma	E/50 /400()	5/50 (400/)	0/50 /40/)	••••••	0/50 (400)	4/50 (00/)	7/50 (440)
Overall Incidence	Total	5/50 (10%) 12/150 (8%)	5/50 (10%) Mean 8%	2/50 (4%) SD 3.46%	Total	2/50 (4%) 10/150 (6.67%)	1/50 (2%) Mean 6.67%	7/50 (14%) SD 6.43%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

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Contract/Lab: All Laboratories Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: WATER Page: 100

			Male				Female	
All Organs: Histiocytic Sarcoma				2/52 (221)				
		0/50 (0%)	1/50 (2%)	0/50 (0%)		2/50 (4%)	0/50 (0%)	0/50 (0%)
verall Incidence	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%	Total	2/150 (1.33%)	Mean 1.33%	SD 2.31%
All Organs: Malignant Lymphoma: Hi or Undifferentiated Cell T	stiocytic, Lyr	nphocytic, Mixed, NOS						
	-	2/50 (4%)	4/50 (8%)	2/50 (4%)	+	10/50 (20%)	9/50 (18%)	8/50 (16%)
verall Incidence	Total	8/150 (5.33%)	Mean 5.33%	SD 2.31%	Total	27/150 (18%)	Mean 18%	SD 2%
All Organs: Mesothelioma: Benign, M	alignant, NO	S 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
verall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%
All Organs: Mesothelioma: Malignant	•••••	0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
verall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%
All Organs: Osteoma		0/50 (00)	0/50 (00/)	0/50 (00)		0/50 (00/)	0/50 (00/)	0/50 (00/)
verall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
All Organs: Osteosarcoma		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
verall Incidence	Total	0/50 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: WATER Page: 101

			Male				Female	
All Organs: Osteosarcoma or Osteoma								
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
Adrenal Cortex: Adenoma		0/50 (404)	4/50 (00()	F/40 (40%)		0/40 (00)	0/50 (00/)	0/50 (00/)
verall Incidence	Total	2/50 (4%) 8/149 (5.37%)	1/50 (2%) Mean 5.4%	5/49 (10%) SD 4.28%	Total	0/49 (0%) 0/149 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
Adrenal Cortex: Plasma Cell Tumor Malignan	nt	0/50 (0%)	0/50 (0%)	0/49 (0%)		0/49 (0%)	0/50 (0%)	0/50 (0%)
verall Incidence	Total	0/50 (0%) 0/149 (0%)	0/50 (0%) Mean 0%	0/49 (0%) SD 0%	Total	0/49 (0%) 0/149 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
Adrenal Cortex: Sarcoma								
verall Incidence	Total	0/50 (0%) 0/149 (0%)	0/50 (0%) Mean 0%	0/49 (0%) SD 0%	Total	0/49 (0%) 0/149 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
drenal Medulla: Pheochromocytoma Benign		0/50 /00()	0/50 (00/)	0/40 (09/)		0/50 (00)	4/50 (00/)	0/50 (00/)
verall Incidence	Total	0/50 (0%) 0/149 (0%)	0/50 (0%) Mean 0%	0/49 (0%) SD 0%	Total	0/50 (0%) 1/150 (0.67%)	1/50 (2%) Mean 0.67%	0/50 (0%) SD 1.15%
Adrenal Medulla: Pheochromocytoma Comple	ex							
verall Incidence	Total	0/50 (0%) 0/149 (0%)	0/50 (0%) Mean 0%	0/49 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

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Report Date:04/29/2009

Route: GAVAGE Vehicle: WATER

Length of Study: CHRONIC

			Male				Female	
*Adrenal Medulla: Pheochromocytoma Malig	jnant	1/50 (2%)	0/50 (0%)	0/49 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/149 (0.67%)	Mean 0.67%	SD 1.15%	Total	0/150 (0%)	Mean 0%	SD 0%
*Adrenal Medulla: Pheochromocytoma: Beni	ign, Complex	κ, Malignant, NOS 1/50 (2%)	0/50 (0%)	0/49 (0%)	•••••	0/50 (0%)	1/50 (2%)	0/50 (0%)
Overall Incidence	Total	1/149 (0.67%)	Mean 0.67%	SD 1.15%	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%
*Bone Marrow: Hemangioma		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/49 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/149 (0%)	Mean 0%	SD 0%
*Bone Marrow: Hemangiosarcoma		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/49 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/149 (0%)	Mean 0%	SD 0%
*Bone Marrow: Plasma Cell Tumor Malign	nant	0/50 (09/)	0/50 (09/)	0/50 (00/)		0/50 (00/)	0/50 (09/)	0/40 (0%)
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/149 (0%)	0/50 (0%) Mean 0%	0/49 (0%) SD 0%
#Bone: Hemangiosarcoma		0/50 (00)	(00)	(201)		2/22 (22)	(70)	2(72 (22))
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Contract/Lab: All Laboratories Tumor Incidence for Selected Control Animal Groups

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Species: MICE Strain: B6C3F1 Route: GAVAGE
Vehicle: WATER

Report Date:04/29/2009

Length of Study: CHRONIC

			Male				Female	
#Bone: Osteoma		0/50 /00/	0/50 (00))/F0		0/50 (00/)	0/50 (00)	0/50 (00/)
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) 0 Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
#Bone: Osteosarcoma		0/50 (00/)	0/50 (00/))/F0		0/50 (0%)	0/50 (00()	0/50 (00/)
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) 0 Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
#Bone: Osteosarcoma or Osteoma		0/50 (0%)	0/50 (00/)	NEO (00/)		0/50 (0%)	0/50 (0%)	0/50 (00/)
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) 0 Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
#Bone: Sarcoma								
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) 0 Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
Brain: Meningioma Benign								
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) 0 Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
Brain: Meningioma Malignant								
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) (Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

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Report Date:04/29/2009

Route: GAVAGE Vehicle: WATER

Length of Study: CHRONIC

			Male				Female	
*Brain: Meningioma: Benign, Mali	gnant, NOS							
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
*Brain: Schwannoma Malignant		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%
*Clitoral/Preputial Gland: Adenoma		- / / / / / / / / / /						
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
*Clitoral/Preputial Gland: Carcinoma	•••••	0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%
*Clitoral/Preputial Gland: Carcinoma or Adenoma	•••••	0/50 (0%)	0/50 (00/)	0/50 (0%)		0/50 (00/)	0/50 (00()	0/50 (00/)
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
*Clitoral/Preputial Gland: Hemangioma								
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Contract/Lab: All Laboratories

Tumor Incidence for Selected Control Animal Groups

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Report Date: 04/29/2009

Species: MICE Strain: B6C3F1 Route: GAVAGE Vehicle: WATER

Length of Study: CHRONIC

			Male				Female	
*Clitoral/Preputial Gland: Hemangiosarcoma								
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
*Clitoral/Preputial Gland: Squamous Cell Carcinoma		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%
#Esophagus: Squamous Cell Carcinoma		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%
#Eye: Sarcoma		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%
#Harderian Gland: Adenoma		0/50 /400/)	44/50 (000)	44/50 (000)		4/50 (00)	7/50 (4.40())	7/50 (440/)
Overall Incidence	Total	6/50 (12%) 28/150 (18.67%)	11/50 (22%) Mean 18.67%	11/50 (22%) SD 5.77%	Total	4/50 (8%) 18/150 (12%)	7/50 (14%) Mean 12%	7/50 (14%) SD 3.46%
#Harderian Gland: Carcinoma								
Overall Incidence	Total	2/50 (4%) 6/150 (4%)	1/50 (2%) Mean 4%	3/50 (6%) SD 2%	Total	4/50 (8%) 4/150 (2.67%)	0/50 (0%) Mean 2.67%	0/50 (0%) SD 4.62%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: WATER Page: 106

			Male				Female	
#Harderian Gland: Carcinoma or Adenoma								
Overall Incidence	Total	7/50 (14%) 32/150 (21.33%)	12/50 (24%) Mean 21.33%	13/50 (26%) SD 6.43%	Total	8/50 (16%) 22/150 (14.67%)	7/50 (14%) Mean 14.67%	7/50 (14%) SD 1.15%
#Harderian Gland: Sarcoma		0/50 (00()	0/50 (0%)	0/50 (0%)		0/50 (00/)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
*Heart: Hemangioma								
Overall Incidence	Total	1/50 (2%) 1/150 (0.67%)	0/50 (0%) Mean 0.67%	0/50 (0%) SD 1.15%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
Heart: Hemangiosarcoma		0/50 (00()	4/50 (00()	0/50 (0%)		0/50 (00()	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/50 (0%) 1/150 (0.67%)	1/50 (2%) Mean 0.67%	0/50 (0%) SD 1.15%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
Heart: Sarcoma		0/50 (00()	0/50 (0%)	0/50 (0%)		0/50 (00/)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
#Intestine Large: Cecum: Carcinoma	•••••	0/50 (004)	0/50 (00/)	4/50 (004)	•••••	0/50 (00/)	0/50 (00/)	0/50 (00/)
Overall Incidence	Total	0/50 (0%) 1/150 (0.67%)	0/50 (0%) Mean 0.67%	1/50 (2%) SD 1.15%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

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Report Date:04/29/2009

Route: GAVAGE Vehicle: WATER

Length of Study: CHRONIC

			Male	Female
#Intestine Large: Cecum: Carcinoma or Adenoma				
Overall Incidence	Total	0/50 (0%) 1/150 (0.67%)	0/50 (0%) 1/50 (2%) Mean 0.67% SD 1.15%	0/50 (0%) 0/50 (0%) 0/50 (0%) Total 0/150 (0%) Mean 0% SD 0%
#Intestine Large: Cecum: Leiomyoma				
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) 0/50 (0%) Mean 0% SD 0%	0/50 (0%) 0/50 (0%) 0/50 (0%) Total 0/150 (0%) Mean 0% SD 0%
#Intestine Large: Colon/Rectum: Leiomyosarcoma				
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) 0/50 (0%) Mean 0% SD 0%	0/50 (0%) 0/50 (0%) 0/50 (0%) Total 0/150 (0%) Mean 0% SD 0%
#Intestine Small: Duodenum: Adenoma				
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) 0/50 (0%) Mean 0% SD 0%	0/50 (0%) 0/50 (0%) 0/50 (0%) Total 0/150 (0%) Mean 0% SD 0%
#Intestine Small: Duodenum: Carcinoma				
Overall Incidence	Total	0/50 (0%) 2/150 (1.33%)	0/50 (0%) 2/50 (4%) Mean 1.33% SD 2.31%	0/50 (0%) 0/50 (0%) 0/50 (0%) Total 0/150 (0%) Mean 0% SD 0%
#Intestine Small: Duodenum: Leiomyosarcoma				
Overall Incidence	Total	0/50 (0%) 0/150 (0%)		0/50 (0%) 0/50 (0%) 0/50 (0%) Total 0/150 (0%) Mean 0% SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

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Report Date: 04/29/2009

Route: GAVAGE Vehicle: WATER

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Male Female #Intestine Small: Duodenum: Polyp Adenomatous 0/50 (0%)(0%)(0%)(0%)0/50 (0%)0/50 (0%)**Overall Incidence** Total 0/150 (0%) Mean 0% SD 0% Total 0/150 (0%) Mean 0% SD 0% #Intestine Small: Ileum: Carcinoma 0/50 (0%)(0%)0/50 (0%)0/50 0/50 0/50 0/50 (0%)**Overall Incidence** SD 0% SD 0% Total 0/150 (0%) Mean 0% Total 0/150 (0%)Mean 0% #Intestine Small: Ileum: Hemangiosarcoma 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)**Overall Incidence** Total 0/150 (0%) Mean 0% SD 0% Total 0/150 (0%) Mean 0% SD 0% #Intestine Small: Ileum: Polyp Adenomatous (0%)(0%)0/50 (0%)(0%)0/50 (0%)0/50 0/50 0/50 Mean 0% **Overall Incidence** Total 0/150 (0%) Mean 0% SD 0% Total 0/150 (0%) SD 0% #Intestine Small: Jejunum: Adenoma 0/50 (0%)(0%)0/50 (0%)0/50 0/50 0/50 (0%)**Overall Incidence** Total 0/150 (0%) Mean 0% SD 0% Total 0/150 Mean 0% SD 0% #Intestine Small: Jejunum: Carcinoma 0/50 (0%)(0%)0/50 (0%)0/50 0/50 (0%)0/50 (0%)**Overall Incidence** 0/150 (0%) SD 0% 0/150 (0%) SD 0% Total Mean 0% Total Mean 0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

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Report Date:04/29/2009

Route: GAVAGE Vehicle: WATER

Length of Study: CHRONIC

			Male	Female
#Intestine Small: Jejunum: Hemangiosarcoma		0/50 /00/)	0/50 (00())	0/50 (00/) 0/50 (00/) 0/50 (00/)
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) 0/50 (0%) Mean 0% SD 0%	0/50 (0%) 0/50 (0%) 0/50 (0%) Total 0/150 (0%) Mean 0% SD 0%
#Intestine Small: Jejunum: Leiomyosarcoma		0/50 (00/)	0/50 (00())	0/50 (0%) 0/50 (0%) 0/50 (0%)
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) 0/50 (0%) Mean 0% SD 0%	0/50 (0%) 0/50 (0%) 0/50 (0%) Total 0/150 (0%) Mean 0% SD 0%
#Intestine Small: Jejunum: Polyp Adenomatous		0/50 (00/)	0/50 (09() 0/50 (09()	0/50 (09/) 0/50 (09/) 0/50 (09/)
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) 0/50 (0%) Mean 0% SD 0%	0/50 (0%) 0/50 (0%) 0/50 (0%) Total 0/150 (0%) Mean 0% SD 0%
#Intestine Small: Site Unspecif Adenoma	ied:	0/50 (00/)	0/50 (09/) 0/50 (09/)	0/60 (09/) 0/60 (09/) 0/60 (09/)
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) 0/50 (0%) Mean 0% SD 0%	0/50 (0%) 0/50 (0%) 0/50 (0%) Total 0/150 (0%) Mean 0% SD 0%
#Intestine Small: Site Unspecif Carcinoma				
Overall Incidence	Total	0/50 (0%) 2/150 (1.33%)	0/50 (0%) 2/50 (4%) Mean 1.33% SD 2.31%	0/50 (0%) 0/50 (0%) 0/50 (0%) Total 0/150 (0%) Mean 0% SD 0%
#Intestine Small: Site Unspecif Carcinoma or Adenoma	ied:			
Overall Incidence	Total	0/50 (0%) 2/150 (1.33%)	0/50 (0%) 2/50 (4%) Mean 1.33% SD 2.31%	0/50 (0%) 0/50 (0%) 0/50 (0%) Total 0/150 (0%) Mean 0% SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

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Report Date: 04/29/2009

Route: GAVAGE Vehicle: WATER

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Male Female #Intestine Small: Site Unspecified: Hemangiosarcoma 0/50 (0%)(0%)(0%)(0%)0/50 (0%)0/50 (0%)**Overall Incidence** Total 0/150 (0%) Mean 0% SD 0% Total 0/150 (0%) Mean 0% SD 0% #Intestine Small: Site Unspecified: Leiomyosarcoma 0/50 (0%)(0%)0/50 (0%)0/50 0/50 0/50 0/50 (0%)SD 0% **Overall Incidence** SD 0% Total 0/150 (0%) Mean 0% Total 0/150 (0%)Mean 0% #Intestine Small: Site Unspecified: **Polyp Adenomatous** 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)**Overall Incidence** Total 0/150 (0%) Mean 0% SD 0% Total 0/150 (0%) Mean 0% SD 0% *Islets, Pancreatic: Adenoma (0%)(2%)0/50 (0%)(2%)0/50 (0%)0/50 1/50 1/50 SD 1.15% SD 1.15% **Overall Incidence** Total 1/150 (0.67%) Mean 0.67% Total 1/150 (0.67%) Mean 0.67% *Islets, Pancreatic: Carcinoma 0/50 (0%)(2%)0/50 (0%)0/50 0/50 0/50 (0%)**Overall Incidence** Total 1/150 (0.67%) Mean 0.67% SD 1.15% Total 0/150 (0%) Mean 0% SD 0% *Islets, Pancreatic: Carcinoma or Adenoma 0/50 (0%)2/50 (4%)0/50 (0%)0/50 (0%)1/50 (2%)0/50 (0%)**Overall Incidence** 2/150 (1.33%) SD 2.31% 1/150 (0.67%) SD 1.15% Total Mean 1.33% Total Mean 0.67%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

Toxicology Data Management System

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Report Date:04/29/2009

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: WATER

Length of Study: CHRONIC

			Male	Female
*Kidney: Renal Tubule: Adenoma				
	.	0/50 (0%)	0/50 (0%) 1/50 (2%)	0/50 (0%) 0/50 (0%) 0/50 (0%)
Overall Incidence	Total	1/150 (0.67%)	Mean 0.67% SD 1.15%	Total 0/150 (0%) Mean 0% SD 0%
*Kidney: Renal Tubule: Carcinoma		(201)		
Overall Incidence	Total	0/50 (0%) 1/150 (0.67%)	1/50 (2%) 0/50 (0%) Mean 0.67% SD 1.15%	0/50 (0%) 0/50 (0%) 0/50 (0%) Total 0/150 (0%) Mean 0% SD 0%
Overall incidence	Total	1/150 (0.67%)	Mean 0.07% SD 1.15%	Total 0/150 (0%) Weath 0% SD 0%
*Kidney: Renal Tubule: Carcinoma or Adenoma		0/50 (00/)	4/50 (00)	0/50 (0%) 0/50 (0%) 0/50 (0%)
Overall Incidence	Total	0/50 (0%) 2/150 (1.33%)	1/50 (2%) 1/50 (2%) Mean 1.33% SD 1.15%	0/50 (0%) 0/50 (0%) 0/50 (0%) Total 0/150 (0%) Mean 0% SD 0%
Overall incluence	Total	2/130 (1.33/0)	Weat 1.55% 3D 1.15%	10tal 0/130 (0/6) Weath 0/6 3D 0/6
*Kidney: Renal Tubule: Hemangioma		0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%) 0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0% SD 0%	Total 0/150 (0%) Mean 0% SD 0%
*Kidney: Renal Tubule: Hemangiosarcoma		0.170 (001)		
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) 0/50 (0%) Mean 0% SD 0%	0/50 (0%) 0/50 (0%) 0/50 (0%) Total 0/150 (0%) Mean 0% SD 0%
Overall incluence	IUlai	0/100 (0%)	IVICALI U% SD U%	Total 0/130 (0%) Wealt 0% 3D 0%
*Kidney: Renal Tubule: Plasma Cell Tumor Maligna	ant	•••••		
		0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%) 0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0% SD 0%	Total 0/150 (0%) Mean 0% SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

Toxicology Data Management System

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Report Date: 04/29/2009

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: WATER

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Male Female *Liver: Cholangiocarcinoma 0/50 (0%)(0%)(0%)(0%)0/50 (0%)0/50 (0%)**Overall Incidence** Total 0/150 (0%) Mean 0% SD 0% Total 0/150 (0%) Mean 0% SD 0% *Liver: **Fibrous Histiocytoma** 0/50 (0%)(0%)0/50 0/50 (0%)0/50 0/50 0/50 (0%)**Overall Incidence** SD 0% SD 0% Total 0/150 (0%) Mean 0% Total 0/150 Mean 0% *Liver: Hemangioma 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)(0%)0/50 **Overall Incidence** Total 0/150 (0%) Mean 0% SD 0% Total 0/150 (0%) Mean 0% SD 0% *Liver: Hemangiosarcoma (2%)(4%)(2%)(0%)0/50 (0%)1/50 2/50 1/50 0/50 **Overall Incidence** Total 4/150 (2.67%) Mean 2.67% SD 1.15% Total 0/150 (0%) Mean 0% SD 0% Hepatoblastoma 1/50 (2%)1/50 (2%)1/50 (2%)0/50 (0%)1/50 (2%)**Overall Incidence** Total 3/150 (2%) Mean 2% SD 0% Total 1/150 (0.67%)Mean 0.67% SD 1.15% *Liver: Hepatocellular Adenoma 24/50 (48%)(68%)33/50 (66%)6/50 (12%)21/50 (42%)14/50 (28%)**Overall Incidence** SD 15.01% Total 91/150 (60.67%) Mean 60.67% SD 11.02% Total 41/150 (27.33%) Mean 27.33%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Vehicle: WATER

Contract/Lab: All Laboratories Tumor Incidence for Selected Control Animal Groups

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Species: MICE Strain: B6C3F1 nor Incidence for Selected Control Animal (

Route: GAVAGE

Report Date: 04/29/2009

Length of Study: CHRONIC

			Male				Female	
*Liver: Hepatocellular Carcinoma		15/50 (30%)	14/50 (28%)	11/50 (22%)		4/50 (8%)	2/50 (4%)	2/50 (4%)
Overall Incidence	Total	40/150 (26.67%)	Mean 26.67%	SD 4.16%	Total	8/150 (5.33%)	Mean 5.33%	SD 2.31%
*Liver: Hepatocellular Carcinoma	or Hepatobl	astoma						
Overall Incidence	Total	16/50 (32%) 42/150 (28%)	14/50 (28%) Mean 28%	12/50 (24%) SD 4%	Total	4/50 (8%) 9/150 (6%)	2/50 (4%) Mean 6%	3/50 (6%) SD 2%
*Liver: Hepatocellular Carcinoma	or Hepatoce	ellular Adenoma 33/50 (66%)	39/50 (78%)	39/50 (78%)		9/50 (18%)	23/50 (46%)	14/50 (28%)
Overall Incidence	Total	111/150 (74%)	Mean 74%	SD 6.93%	Total	46/150 (30.67%)	Mean 30.67%	SD 14.19%
*Liver: Hepatocellular Carcinoma, Hepatoblastoma	Hepatocelli							
Overall Incidence	Total	34/50 (68%) 112/150 (74.67%)	39/50 (78%) Mean 74.67%	39/50 (78%) SD 5.77%	Total	9/50 (18%) 47/150 (31.33%)	23/50 (46%) Mean 31.33%	15/50 (30%) SD 14.05%
*Liver: Hepatocholangiocarcinoma	a	4/50 (20()	0/50 (0%)	0/50 (09/)		0/50 (0%)	0/50 (09/)	0/50 (00/)
Overall Incidence	Total	1/50 (2%) 1/150 (0.67%)	0/50 (0%) Mean 0.67%	0/50 (0%) SD 1.15%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
*Liver: Hepatocholangioma		0/50 (09/)	0/50 (0%)	0/50 (09/)		0/50 (09/)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

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Report Date:04/29/2009

Route: GAVAGE Vehicle: WATER

Length of Study: CHRONIC

			Male				Female	
*Liver: Ito Cell Tumor Benign		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%
*Liver: Ito Cell Tumor Malignant		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%
*Liver: Plasma Cell Tumor Malign	ant	0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%
*Liver: Sarcoma		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%
*Lung: Adenoma		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%
*Lung: Alveolar/Bronchiolar Aden	noma	40/50 (000)	0/50 /400/	40/50 (00%)		4/50 (00()	0/50 /400/	0/50 (40/)
Overall Incidence	Total	10/50 (20%) 29/150 (19.33%)	9/50 (18%) Mean 19.33%	10/50 (20%) SD 1.15%	Total	4/50 (8%) 12/150 (8%)	6/50 (12%) Mean 8%	2/50 (4%) SD 4%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

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Report Date:04/29/2009

Species: MICE **Strain:** B6C3F1

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Route: GAVAGE Vehicle: WATER

			Male				Female					
Lung: Alveolar/Bronchiolar Carcinoma 6/50 (13%) 3/50 (6%) 7/50 (14%) 2/50 (4%) 1/50 (3%) 1/50 (2%)												
Overall Incidence	Total	6/50 (12%) 16/150 (10.67%)	3/50 (6%) Mean 10.67%	7/50 (14%) SD 4.16%	Total	2/50 (4%) 4/150 (2.67%)	1/50 (2%) Mean 2.67%	1/50 (2%) SD 1.15%				
Lung: Alveolar/Bronchiolar C Adenoma	arcinoma or Alv	veolar/Bronchiolar										
Overall Incidence	Total	16/50 (32%) 44/150 (29.33%)	12/50 (24%) Mean 29.33%	16/50 (32%) SD 4.62%	Total	5/50 (10%) 15/150 (10%)	7/50 (14%) Mean 10%	3/50 (6%) SD 4%				
Lung: Fibrosarcoma		0/50 (00/)	0/50 (0%)	0/50 (0%)		0/50 (00()	0/50 /0%	0/50 (00/)				
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%				
ung: Fibrous Histiocytoma		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)				
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%				
_ung: Hemangiosarcoma		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)				
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%				
Lung: Plasma Cell Tumor Mal	lignant	0/50 (0%)	0/50 (00/)	0/50 (00/)		0/50 (00()	0/50 (00/)	0/50 /00/				
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%				

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Route: GAVAGE

Vehicle: WATER

Tumor Incidence for Selected Control Animal Groups

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Contract/Lab: All Laboratories

Report Date:04/29/2009

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

			Male				Female	
*Lung: Sarcoma		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%
#Lymph Node: Fibrous Histiocytoma					•••••			
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
#Lymph Node: Hemangioma					•••••			
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
#Lymph Node: Hemangiosarcoma		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%
#Lymph Node: Plasma Cell Tumor Maligr	nant				•••••			
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
#Lymph Node: Sarcoma					•••••	(00)		0/20 (00)
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%

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^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

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Report Date:04/29/2009

Route: GAVAGE Vehicle: WATER

Length of Study: CHRONIC

			Male		Female
#Lymph Node, Bronchial: Hemangiosarcoma					
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) 0/50 (0%) Mean 0% SD 0%	0/50 (0%) Total 0/150 (0%)	0/50 (0%) 0/50 (0%) Mean 0% SD 0%
#Lymph Node, Mandibular: Fibrous Histiocytoma		0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%) 0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0% SD 0%	Total 0/150 (0%)	Mean 0% SD 0%
#Lymph Node, Mandibular: Hemangiosarcoma		0/50 (00/)	0/50 (00)	0/50 (00)	0/50 (00)
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) 0/50 (0%) Mean 0% SD 0%	0/50 (0%) Total 0/150 (0%)	0/50 (0%) 0/50 (0%) Mean 0% SD 0%
#Lymph Node, Mandibular: Mast Cell Tumor Malignant		0/50 (0%)	1/50 (2%) 0/50 (0%)	0/50 (0%)	0/50 (0%) 0/50 (0%)
Overall Incidence	Total	1/150 (0.67%)	Mean 0.67% SD 1.15%	Total 0/150 (0%)	Mean 0% SD 0%
#Lymph Node, Mandibular: Plasma Cell Tumor Maligna	nt	0/50 (00/)	0/50 (0%) 0/50 (0%)	0/50 (00)	0/50 (0%) 0/50 (0%)
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) 0/50 (0%) Mean 0% SD 0%	0/50 (0%) Total 0/150 (0%)	0/50 (0%) 0/50 (0%) Mean 0% SD 0%
#Lymph Node, Mesenteric: Fibrous Histiocytoma					
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) 0/50 (0%) Mean 0% SD 0%	0/50 (0%) Total 0/150 (0%)	0/50 (0%) 0/50 (0%) Mean 0% SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: WATER Page: 118

			Male				Female	
Lymph Node, Mesenteric: Hemangioma								
_		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%
Lymph Node, Mesenteric: Hemangiosarcoma								4/50 (00)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	1/50 (2%)
verall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%
Lymph Node, Mesenteric:								
Plasma Cell Tumor Malignant								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
verall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%
Mammary Gland: Adenoacanthoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
verall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%
//ammary Gland: Adenoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	1/50 (2%)	0/50 (0%)
verall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%
Mammary Gland: Carcinoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		2/50 (4%)	0/50 (0%)	1/50 (2%)
verall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	3/150 (2%)	Mean 2%	SD 2%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

: May2009

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: WATER Page: 119

			Male				Female				
#Mammary Gland: Carcinoma or Adenoma 0/50 (0%) 0/50 (0%) 0/50 (0%) 2/50 (4%) 1/50 (2%) 1/50 (2%)											
verall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	2/50 (4%) 4/150 (2.67%)	1/50 (2%) Mean 2.67%	1/50 (2%) SD 1.15%			
Mammary Gland: Fibroadenoma		2/22 (22)	0.000	(00)		-()		2/20 (201)			
verall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%			
Mammary Gland: Fibroma, Fibroadenoma	a or Adenoma	0/50 (00/)	0/50 (00()	0/50 (00/)		0/50 (00)	4/50 (00/)	0/50 (00/)			
verall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 1/150 (0.67%)	1/50 (2%) Mean 0.67%	0/50 (0%) SD 1.15%			
Mammary Gland: Fibroma, Fibroadenoma			0/50 (0%)	0/50 (0%)		2/50 (4%)	1/50 (2%)	1/50 (2%)			
verall Incidence	Total	0/30 (0%)	Mean 0%	SD 0%	Total	4/150 (2.67%)	Mean 2.67%	SD 1.15%			
Mesentery: Fibrosarcoma											
overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	1/50 (2%) 1/150 (0.67%)	0/50 (0%) Mean 0.67%	0/50 (0%) SD 1.15%			
Mesentery: Hemangioma		0/50 (00()	0/50 (00/)	0/50 /00/		0/50 (00/)	0/50 (0%)	0/50 /00/			
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)			

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: WATER Page: 120

			Male				Female	
Mesentery: Hemangiosarcoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%
Mesentery: Sarcoma		0.700		2(-2 (22)		- ()	(00)	0.750 (001)
huanall luaidan aa	Tatal	0/50 (0%)	0/50 (0%)	0/50 (0%)	Tatal	0/50 (0%)	0/50 (0%)	0/50 (0%)
overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%
Nose:								
Mast Cell Tumor Malig	nant	0/50 (00/)	0/50 (00/)	0/50 (00/)		0/50 (00/)	0/50 (00/)	0/40 (00/)
verall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/149 (0%)	0/50 (0%) Mean 0%	0/49 (0%) SD 0%
Oral Cavity (Oral Mucosa Papilloma Squamous o		nx, Tooth, Gingiva):						
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
verall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%
Oral Cavity (Oral Mucosa Squamous Cell Carcin	, Tongue, Phary	nx, Tooth, Gingiva):						
•		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	1/50 (2%)
verall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%
Oral Cavity (Oral Mucosa Squamous Cell Carcin Papilloma	, Tongue, Phary	Squamous, or						
		0/50 (0%)	0/50 (0%)	0/50 (0%) SD 0%		0/50 (0%)	0/50 (0%)	1/50 (2%)
Overall Incidence	Total	0/150 (0%)	Mean 0%		Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: WATER Page: 121

	Male		Female
*Ovary: Choriocarcinoma		0/50 (0%)	0/50 (0%) 0/50 (0%)
Overall Incidence	Tota	al 0/150 (0%)	Mean 0% SD 0%
*Ovary: Cystadenoma			
Overall Incidence	Tota	1/50 (2%) al 11/150 (7.33%)	7/50 (14%) 3/50 (6%) Mean 7.33% SD 6.11%
*Ovary: Fibrous Histiocytoma			
Overall Incidence	Tota	0/50 (0%) al 0/150 (0%)	0/50 (0%) 0/50 (0%) Mean 0% SD 0%
*Ovary: Granulosa Cell Tumor Benign		0/50 (0%)	0/50 (0%) 0/50 (0%)
Overall Incidence	Tota	` '	Mean 0% SD 0%
*Ovary: Granulosa Cell Tumor Malignant		0/50 (0%)	
Overall Incidence	Tota	` ,	0/50 (0%) 0/50 (0%) Mean 0% SD 0%
*Ovary: Granulosa Cell Tumor: Benign, Malignant, NOS		0/20 (00)	
Overall Incidence	Tota	0/50 (0%) al 0/150 (0%)	0/50 (0%) 0/50 (0%) Mean 0% SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Page: 122

Report Date:04/29/2009

Route: GAVAGE Vehicle: WATER

Length of Study: CHRONIC

	Male		Female	
*Ovary: Hemangioma		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%
*Ovary: Hemangiosarcoma		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%
*Ovary: Leiomyosarcoma				
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
*Ovary: Luteoma		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/30 (0%)	Mean 0%	SD 0%
*Ovary: Plasma Cell Tumor Malignant		2/52 (201)		
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
*Ovary: Teratoma Benign		0/50 (004)	0/50 (00/)	0/50 (00/)
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Page: 123

Report Date:04/29/2009

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Route: GAVAGE Vehicle: WATER

			Male				Female	
*Ovary: Teratoma Malignant								
Overall Incidence					Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
*Ovary: Tubulostromal Adenoma								
Overall Incidence					Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
*Pancreas: Adenoma								
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/49 (0%) 0/148 (0%)	0/50 (0%) Mean 0%	0/49 (0%) SD 0%
*Pancreas: Carcinoma		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/49 (0%)	0/50 (0%)	0/49 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/148 (0%)	Mean 0%	SD 0%
*Pancreas: Carcinoma or Adenoma								
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/49 (0%) 0/148 (0%)	0/50 (0%) Mean 0%	0/49 (0%) SD 0%
*Pituitary Gland: Pars Distalis	or Unspecif	ied Site:						
Overall Incidence	Total	1/50 (2%) 2/148 (1.35%)	1/50 (2%) Mean 1.33%	0/48 (0%) SD 1.15%	Total	3/50 (6%) 6/149 (4.03%)	1/50 (2%) Mean 4.03%	2/49 (4%) SD 2%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

trol Animal Groups

Page: 124

Report Date:04/29/2009

Route: GAVAGE Vehicle: WATER

Length of Study: CHRONIC

			Male				Female					
*Pituitary Gland: Pars Distalis or Unspecified Site: Carcinoma												
		1/50 (2%)	0/50 (0%)	0/48 (0%)		0/50 (0%)	0/50 (0%)	0/49 (0%)				
Overall Incidence	Total	1/148 (0.68%)	Mean 0.67%	SD 1.15%	Total	0/149 (0%)	Mean 0%	SD 0%				
*Pituitary Gland: Pars Distalis Carcinoma or Adenoma				•••••		•••••						
		2/50 (4%)	1/50 (2%)	0/48 (0%)		3/50 (6%)	1/50 (2%)	2/49 (4%)				
Overall Incidence	Total	3/148 (2.03%)	Mean 2%	SD 2%	Total	6/149 (4.03%)	Mean 4.03%	SD 2%				
*Pituitary Gland: Pars Interme Adenoma	edia:											
		0/50 (0%)	0/50 (0%)	0/48 (0%)		1/50 (2%)	1/50 (2%)	2/49 (4%)				
Overall Incidence	Total	0/148 (0%)	Mean 0%	SD 0%	Total	4/149 (2.68%)	Mean 2.69%	SD 1.2%				
*Pituitary Gland: Pars Interme Carcinoma or Adenoma		0/50 (0%)	0/50 (0%)	0/48 (0%)		1/50 (2%)	1/50 (2%)	2/49 (4%)				
Overall Incidence	Total	0/30 (0 %)	Mean 0%	SD 0%	Total	4/149 (2.68%)	Mean 2.69%	SD 1.2%				
*Prostate: Adenoma												
		0/50 (0%)	0/50 (0%)	0/50 (0%)								
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%								
*Prostate: Carcinoma or Adenoma				•••••	•••••	•••••						
		0/50 (0%)	0/50 (0%)	0/50 (0%)								
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%								

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

. May 2000

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: WATER Page: 125

			Male				Female	
*Prostate: Hemangioma		0(50 (00))	0/50 (00/)	0/50 (00/)				
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%				
*Salivary Glands: Carcinoma		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/49 (0%)	0/50 (0%)	0/49 (0%)
Overall Incidence	Total	0/30 (0%)	Mean 0%	SD 0%	Total	0/148 (0%)	Mean 0%	SD 0%
*Salivary Glands: Carcinoma or Adenoma								
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/49 (0%) 0/148 (0%)	0/50 (0%) Mean 0%	0/49 (0%) SD 0%
*Salivary Glands: Mast Cell Tumor Malignant		0/50 (0%)	1/50 (2%)	0/50 (0%)		0/49 (0%)	0/50 (0%)	0/49 (0%)
Overall Incidence	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%	Total	0/49 (0%)	Mean 0%	SD 0%
#Seminal Vesicle: Adenoma								
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%				
#Skeletal Muscle: Fibrosarcoma		0/50 /00()	0/50 (00)	0/50 (00/)		0/50 (00/)	0/50 (00()	0/50 (00()
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Toxicology Data Management SystemTumor Incidence for Selected Control Animal Groups

Page: 126 Report Date: 04/29/2009

Species: MICE Strain: B6C3F1

Route: GAVAGE Vehicle: WATER

Length of Study: CHRONIC

			Male				Female	
Skeletal Muscle: Hemangiosarcoma								
verall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	1/50 (2%) 1/150 (0.67%)	0/50 (0%) Mean 0.67%	0/50 (0%) SD 1.15%
verali ilicidence	ı olal	0/130 (0%)	iviean 0%	3D 0%	ı Olai	1/150 (0.67%)	wearr 0.07%	3D 1.13%
Skeletal Muscle: Myxosarcoma								
	T-1-1	0/50 (0%)	0/50 (0%)	0/50 (0%)	T-1-1	0/50 (0%)	0/50 (0%)	0/50 (0%)
verall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%
Skeletal Muscle: Rhabdomyosarcoma	••••••							
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
verall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%
keletal Muscle: Rhabdomyosarcoma or Rhabo	domyom	a						
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
erall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%
keletal Muscle: Sarcoma	•••••							
		0/50 (0%)	1/50 (2%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
verall Incidence	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%	Total	0/150 (0%)	Mean 0%	SD 0%
kin: Basal Cell Adenoma or Basos	quamou		0/50 (00)	0/50 (00)		0/50 (00)	0/50 (00/)	0/50 (00/)
and the statement	T-1-1	0/50 (0%)	0/50 (0%)	0/50 (0%)	T-1-1	0/50 (0%)	0/50 (0%)	0/50 (0%)
verall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Contract/Lab: All Laboratories Tumor Incid

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: WATER Page: 127

			Male				Female	
Skin: Basal Cell Adenoma, E Trichoepithelioma	Basosquamous [*]	Tumor Benign, or						
,		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
verall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%
Skin:		•••••				•••••		
Basal Cell Carcinoma		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
verall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%
Skin: Basal Cell Carcinoma (NOS)		ous Tumor (malignant o						
•		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
verall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%
Basal Cell Carcinoma, Tumor (benign, malign	ant or NOS), or	Trichoepithelioma 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Basal Cell Carcinoma, Tumor (benign, malign		Trichoepithelioma	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
	Total Toma, Carcinonoma, Adenoma,	Trichoepithelioma 0/50 (0%) 0/150 (0%) ma, Basosq. Tumor (M Papilloma, Sq	` '	` '	Total	` ,	` ,	` '
Basal Cell Carcinoma, Tumor (benign, malign everall Incidence Skin: Basal or Sq. Cell Carci or B), Basal Cell Adend Papilloma, Keratoacan	Total Toma, Carcinonoma, Adenoma,	Trichoepithelioma 0/50 (0%) 0/150 (0%) ma, Basosq. Tumor (M Papilloma, Sq pithelioma	Mean 0%	SD 0%	Total Total	0/150 (0%) [′]	Mean 0%	SD 0%
Basal Cell Carcinoma, Tumor (benign, malign everall Incidence Skin: Basal or Sq. Cell Carci or B), Basal Cell Adend Papilloma, Keratoacan	Total noma, Carcinonoma, Adenoma, thoma, Trichoe	Trichoepithelioma 0/50 (0%) 0/150 (0%) ma, Basosq. Tumor (M Papilloma, Sq pithelioma 0/50 (0%)	Mean 0% / O/50 (0%)	SD 0% /		0/150 (0%) ´	Mean 0%	SD 0% /
Basal Cell Carcinoma, Tumor (benign, malign everall Incidence Skin: Basal or Sq. Cell Carci or B), Basal Cell Adend Papilloma, Keratoacan	Total Toma, Carcinonoma, Adenoma, thoma, Trichoe	Trichoepithelioma 0/50 (0%) 0/150 (0%) ma, Basosq. Tumor (M Papilloma, Sq pithelioma 0/50 (0%) 0/150 (0%)	Mean 0% 0/50 (0%) Mean 0%	SD 0% (0%) SD 0%		0/150 (0%) ´ 0/50 (0%) 0/50 (0%)	Mean 0% 0/50 (0%) Mean 0%	SD 0% / 0/50 (0%) SD 0%
Basal Cell Carcinoma, Tumor (benign, malign everall Incidence Skin: Basal or Sq. Cell Carci or B), Basal Cell Adend Papilloma, Keratoacan everall Incidence	Total Toma, Carcinonoma, Adenoma, thoma, Trichoe	Trichoepithelioma 0/50 (0%) 0/150 (0%) ma, Basosq. Tumor (M Papilloma, Sq pithelioma 0/50 (0%)	Mean 0% / O/50 (0%)	SD 0% /		0/150 (0%) ´	Mean 0%	SD 0% /

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

Toxicology Data Management System Contract/Lab: All Laboratories

Tumor Incidence for Selected Control Animal Groups

Page: 128

Report Date:04/29/2009

Route: GAVAGE Vehicle: WATER

Length of Study: CHRONIC

			Male				Female	
#Skin: Fibroma		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (09/)	0/50 (09/)
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
#Skin: Fibroma, Fibrosarcoma, Fibrous Histiocytoma	Sarcoma, My	xoma, Myxosarcoma, o	r					
Overall Incidence	Total	0/50 (0%) 1/150 (0.67%)	1/50 (2%) Mean 0.67%	0/50 (0%) SD 1.15%	Total	1/50 (2%) 5/150 (3.33%)	4/50 (8%) Mean 3.33%	0/50 (0%) SD 4.16%
#Skin: Fibrosarcoma		0/50 (0%)	1/50 (2%)	0/50 (0%)		0/50 (0%)	3/50 (6%)	0/50 (0%)
Overall Incidence	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%	Total	3/150 (2%)	Mean 2%	SD 3.46%
#Skin: Fibrosarcoma, Sarcoma Histiocytoma		a, or Fibrous						0/50 (0%)
Overall Incidence	Total	0/50 (0%) 1/150 (0.67%)	1/50 (2%) Mean 0.67%	0/50 (0%) SD 1.15%	Total	1/50 (2%) 5/150 (3.33%)	4/50 (8%) Mean 3.33%	0/50 (0%) SD 4.16%
#Skin: Fibrous Histiocytoma		0/50 (00()	0/50 /00/	0/50 (00/)		0/50 (0%)	4/50 (20()	0/50 /00/
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 1/150 (0.67%)	1/50 (2%) Mean 0.67%	0/50 (0%) SD 1.15%
#Skin: Granular Cell Tumor Ber	nign	0/50 (00()	0/50 (00/)	0/50 (00)		0/50 (00/)	0/50 (00/)	0/50 (00/)
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

Contract/Lab: All Laboratories

Toxicology Data Management System Tumor Incidence for Selected Control Animal Groups Page: 129

Report Date:04/29/2009

Route: GAVAGE Vehicle: WATER

Length of Study: CHRONIC

			Male				Female	
Skin: Hemangioma								
Overall Incidence	Total	0/50 (0%) 1/150 (0.67%)	1/50 (2%) Mean 0.67%	0/50 (0%) SD 1.15%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
Skin: Hemangiosarcoma								
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
Skin: Liposarcoma	•••••							
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
Skin: Myxosarcoma	••••	0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%
Skin: Neurofibrosarcoma or S		malignant or NOS) 0/50 (0%)	1/50 (2%)	0/50 (0%)		0/50 (0%)	2/50 (4%)	0/50 (0%)
Overall Incidence	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%	Total	2/150 (1.33%)	Mean 1.33%	SD 2.31%
Skin: Neurofibrosarcoma, Net malignant or NOS)	urofibroma, or	, ,						
Overall Incidence	Total	0/50 (0%) 1/150 (0.67%)	1/50 (2%) Mean 0.67%	0/50 (0%) SD 1.15%	Total	0/50 (0%) 2/150 (1.33%)	2/50 (4%) Mean 1.33%	0/50 (0%) SD 2.31%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Contract/Lab: All Laboratories Species: MICE

Strain: B6C3F1 Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: WATER Page: 130

			Male				Female	
Skin: Osteosarcoma								
verall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
Skin: Sarcoma		0/50 (00/)	0/50 (00/)	0/50 (001)		4/50 (00)	0/50 (00/)	0/50 (00)
verall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	1/50 (2%) 1/150 (0.67%)	0/50 (0%) Mean 0.67%	0/50 (0%) SD 1.15%
Skin: Schwannoma Malignant	•••••	0/50 (0%)	1/50 (2%)	0/50 (0%)	•••••	0/50 (0%)	2/50 (4%)	0/50 (0%)
verall Incidence	Total	0/50 (0%) 1/150 (0.67%)	1/50 (2%) Mean 0.67%	0/50 (0%) SD 1.15%	Total	0/50 (0%) 2/150 (1.33%)	2/50 (4%) Mean 1.33%	0/50 (0%) SD 2.31%
Skin: Squamous Cell Carcinon	na							
verall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
Skin: Squamous Cell Carcinor Basosquamous Tumor (ı			0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
verall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%
Skin: Squamous Cell Papillom	a	0/50 (00()	0/50 /09/	0/50 (00/)		0/50 (00/.)	0/50 (00/)	0/50 (00/)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

Contract/Lab: All Laboratories

Toxicology Data Management System

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Report Date:04/29/2009

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: WATER

Length of Study: CHRONIC

			Male				Female	
Skin: Squamous Cell Papillo	ma or Papillom							
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
verall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%
Skin: Squamous Cell Papillo Carcinoma or Keratoac		-						
verall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
Skin: Squamous Cell Papillo verall Incidence		or Keratoacanthoma 0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
kin: Trichoepithelioma		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
verall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%
Skin: Sebaceous Gland: Adenoma		0/50 (00/.)	0/50 (00()	0/50 (00/)		0/50 (0%)	0/50 (00/)	0/50 (00/)
verall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
Skin: Sebaceous Gland: Carcinoma		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
verall Incidence	Total	` ,	` ,	0/50 (0%) SD 0%	Total	` '	` ,	0/50 (0%) SD 0%
verali incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Strain: B6C3F1

Contract/Lab: All Laboratories Species: MICE

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: WATER Page: 132

			Male				Female	
Skin: Sebaceous Gland: Carcinoma or Adenoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%
Spinal Cord: Meningioma Malignant		0/50 (00/)	0/50 (00/)	0/50 (00/)		0(50 (004)	0/50 (004)	0/50 (00/)
	T-1-1	0/50 (0%)	0/50 (0%)	0/50 (0%)	T-1-1	0/50 (0%)	0/50 (0%)	0/50 (0%)
verall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%
Spleen: Fibrous Histiocytoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/49 (0%)
verall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/149 (0%)	Mean 0%	SD 0%
Spleen: Hemangioma		0/50 (00/)	0/50 (00/)	0/50 (00)		0(50 (004)	4/50 (00)	0/40 (00/)
	.	0/50 (0%)	0/50 (0%)	0/50 (0%)	.	0/50 (0%)	1/50 (2%)	0/49 (0%)
verall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	1/149 (0.67%)	Mean 0.67%	SD 1.15%
Spleen: Hemangiosarcoma								
_		2/50 (4%)	1/50 (2%)	1/50 (2%)		1/50 (2%)	0/50 (0%)	4/49 (8%)
verall Incidence	Total	4/150 (2.67%)	Mean 2.67%	SD 1.15%	Total	5/149 (3.36%)	Mean 3.39%	SD 4.25%
Spleen: Mast Cell Tumor Malignant			(00)	(00)			(00)	(20)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/49 (0%)
verall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/149 (0%)	Mean 0%	SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

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Report Date:04/29/2009

Route: GAVAGE Vehicle: WATER

Length of Study: CHRONIC

			Male				Female	
Spleen: Plasma Cell Tumor Malignan	t							
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/49 (0%)
verall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/149 (0%)	Mean 0%	SD 0%
Stomach, Forestomach: Mast Cell Tumor Malignant		0/50 (00/)	0/50 (0%)	0/50 /00/)		0/50 /00/)	0/50 (00/)	0/50 (00/)
verall Incidence	Total	0/50 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
veran incidence	TOTAL	0/150 (0%)	wean 0%	SD 0%	ı olal	0/150 (0%)	wean 0%	SD 0%
Stomach, Forestomach: Squamous Cell Carcinoma				- 1 1				
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
verall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%
Stomach, Forestomach: Squamous Cell Carcinoma o			1/50 (2%)	2/50 (4%)	•••••	1/50 (2%)	0/50 (0%)	2/50 (4%)
verall Incidence	Total	3/150 (2%)	Mean 2%	2/30 (4%) SD 2%	Total	3/150 (2%)	Mean 2%	2/30 (4 <i>%</i>) SD 2%
verali iliciuelice	TOtal	3/130 (2/8)	Weall 270	3D 2/6	ı Olai	3/130 (2/6)	ivicaii 270	3D 270
Stomach, Forestomach: Squamous Cell Papilloma								
		0/50 (0%)	1/50 (2%)	2/50 (4%)		1/50 (2%)	0/50 (0%)	2/50 (4%)
verall Incidence	Total	3/150 (2%)	Mean 2%	SD 2%	Total	3/150 (2%)	Mean 2%	SD 2%
Stomach, Glandular: Adenoma		0/50 /00/	0/50 (0%)	0/50 (00/)		0/50 (00/)	0/50 (00/)	0/50 (00/)
	.	0/50 (0%)	0/50 (0%)	0/50 (0%)	-	0/50 (0%)	0/50 (0%)	0/50 (0%)
verall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

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Report Date:04/29/2009

Route: GAVAGE Vehicle: WATER

Length of Study: CHRONIC

			Male		Female	
#Stomach, Glandular: Carcinoma						
Occupation of the second	T-1-1	0/50 (0%)	0/50 (0%) 0/50	` ,	0/50 (0%) 0/50 (0%) 0/50 (0%)	
Overall Incidence	Total	0/150 (0%)	Mean 0% SE	D 0% Total	0/150 (0%) Mean 0% SD 0%	
#Stomach, Glandular: Carcinoma or Adenoma		0/50 (00()	0/50 (09/) 0/50	(00()	0/50 (09/) 0/50 (09/) 0/50 (09/)	
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) 0/50 Mean 0% SE	(0%) D 0% Total	0/50 (0%) 0/50 (0%) 0/50 (0%) 0/150 (0%) Mean 0% SD 0%	
					0,100 (0,0)	
*Testes: Adenoma						
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) 0/50 Mean 0% SE	(0%) D 0%		
		` ,				
*Testes: Hemangiosarcoma						
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) 0/50 Mean 0% SE	(0%) D 0%		
Overall includince	Total	0/130 (070)	WCarr 070 CL			
*Thymus: Thymoma Benign						
Overall Incidence	Total	0/47 (0%) 0/137 (0%)	0/47 (0%) 0/43 Mean 0% SE	(0%) D 0% Total	0/49 (0%) 0/48 (0%) 0/47 (0%) 0/144 (0%) Mean 0% SD 0%	
Overali ilicidence	ı Ulai	0/13/ (070)	iviedii U% SL	7 0 /0 10tal	0/144 (0/0) Wealt 0/0 5D 0%	
*Thymus: Thymoma Malignant		0.117 (001)	0/47 (00/)	(001)	0/40 (001)	
Overall Incidence	Total	0/47 (0%) 0/137 (0%)	0/47 (0%) 0/43 Mean 0% SE	(0%) D 0% Total	0/49 (0%) 0/48 (0%) 0/47 (0%) 0/144 (0%) Mean 0% SD 0%	
Overall incluence	IUlai	U/13/ (U70)	iviean 0% SL	0 0 /0 TOTAL	0/144 (0/0) Weatt 0/0 SD 0/0	

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

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Report Date:04/29/2009

Route: GAVAGE Vehicle: WATER

Length of Study: CHRONIC

			Male				Female	
*Thymus: Thymoma: Benign, Malignar	nt, NOS	0/47 (0%)	0/47 (0%)	0/43 (0%)		0/49 (0%)	0/48 (0%)	0/47 (0%)
Overall Incidence	Total	0/137 (0%)	Mean 0%	SD 0%	Total	0/144 (0%)	Mean 0%	SD 0%
*Thyroid Gland: Adenoma		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/49 (0%)	0/49 (0%)	0/48 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/146 (0%)	Mean 0%	SD 0%
*Thyroid Gland: C-Cell: Carcinoma		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/49 (0%)	0/49 (0%)	0/48 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/146 (0%)	Mean 0%	SD 0%
*Thyroid Gland: C-Cell: Carcinoma or Adenoma		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/49 (0%)	0/49 (0%)	0/48 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/146 (0%)	Mean 0%	SD 0%
*Thyroid Gland: Follicular Cell: Adenoma		0/50 (0%)	1/50 (2%)	2/50 (4%)		2/49 (4%)	0/49 (0%)	1/48 (2%)
Overall Incidence	Total	3/150 (2%)	Mean 2%	SD 2%	Total	3/146 (2.05%)	Mean 2.05%	SD 2.04%
*Thyroid Gland: Follicular Cell: Carcinoma		4/50 (00)	0/50 (00)	0/50 (00)		0/40 (00%)	0/40 (00)	0/40 (00/)
Overall Incidence	Total	1/50 (2%) 1/150 (0.67%)	0/50 (0%) Mean 0.67%	0/50 (0%) SD 1.15%	Total	0/49 (0%) 0/146 (0%)	0/49 (0%) Mean 0%	0/48 (0%) SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

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Report Date:04/29/2009

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Route: GAVAGE Vehicle: WATER

			Male				Female	
Thyroid Gland: Follicular Cell: Carcinoma or Adenoma								
Carcinolla of Adenolla		1/50 (2%)	1/50 (2%)	2/50 (4%)		2/49 (4%)	0/49 (0%)	1/48 (2%)
Overall Incidence	Total	4/150 (2.67%)	Mean 2.67%	SD 1.15%	Total	3/146 (2.05%)	Mean 2.05%	SD 2.04%
Tissue NOS: Carcinoma		0/50 (00/)	0/50 (00/)	0/50 (00)		0/50 (00)	0/50 (00/)	0/50 (00/)
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
#Tissue NOS:								
Hemangiosarcoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%
Tissue NOS: Plasma Cell Tumor Malignant	:							
_		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%
Tissue NOS: Schwannoma Malignant							•••••	•••••
John Manner Mangham		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%
Tongue: Fibroma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

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Report Date:04/29/2009

Route: GAVAGE Vehicle: WATER

Length of Study: CHRONIC

			Male				Female	
#Tongue: Squamous Cell Carcinom	ıa	0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	1/50 (2%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%
#Tongue: Squamous Cell Carcinom	na or Papillon		0/50 (00/)	0/50 (00/)	•••••	0/50 (00/)	0/50 (00/)	4/50 (00()
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 1/150 (0.67%)	0/50 (0%) Mean 0.67%	1/50 (2%) SD 1.15%
#Tongue: Squamous Cell Papilloma	a	0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%
#Tooth: Odontoma		0/50 (0%)	0/50 (0%)	0/50 (0%)	•••••	0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%
*Urinary Bladder: Hemangioma		(IE) (O)()	0/50 (00)	0/50 (00)		0/50 /00/	2/42 (22/)	0/50 (00/)
Overall Incidence	Total	1/50 (2%) 1/150 (0.67%)	0/50 (0%) Mean 0.67%	0/50 (0%) SD 1.15%	Total	0/50 (0%) 0/149 (0%)	0/49 (0%) Mean 0%	0/50 (0%) SD 0%
*Urinary Bladder: Hemangiosarcoma		0/50 (00/)	0/50 (00)	0/50 (00)		0/50 /00/	0/40 (00/)	0/50 (00/)
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/149 (0%)	0/49 (0%) Mean 0%	0/50 (0%) SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

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Report Date: 04/29/2009

Route: GAVAGE Vehicle: WATER

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Male Female *Urinary Bladder: **Plasma Cell Tumor Malignant** 0/50 (0%)(0%)(0%)(0%)0/49 (0%)0/50 (0%)**Overall Incidence** Total 0/150 (0%) Mean 0% SD 0% Total 0/149 (0%) Mean 0% SD 0% *Urinary Bladder: Sarcoma 0/50 (0%)(0%)0/50 (0%)0/50 0/50 0/50 (0%)**Overall Incidence** SD 0% SD 0% Total 0/150 (0%) Mean 0% Total 0/149 Mean 0% #Uterus: Adenoma 0/50 (0%)0/50 (0%)0/50 (0%)**Overall Incidence** Total 0/150 (0%) Mean 0% SD 0% #Uterus: Carcinoma 0/50 (0%)0/50 (0%)Mean 0% **Overall Incidence** Total 0/150 (0%) SD 0% #Uterus: Hemangioma 0/50 (0%)(0%)2/50 (4%)**Overall Incidence** Total 2/150 (1.33%) Mean 1.33% SD 2.31% **#Uterus:** Hemangiosarcoma 0/50 (0%)0/50 (0%)0/50 (0%)**Overall Incidence** SD 0% Total 0/150 (0%) Mean 0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

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Report Date:04/29/2009

Contract/Lab: All Laboratories
Species: MICF

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

Route: GAVAGE Vehicle: WATER

	Male			Female	
#Uterus: Leiomyoma		0/50) (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	To	otal 0/150	(0%)	Mean 0%	SD 0%
#Uterus: Leiomyosarcoma		0/50			
Overall Incidence	т	otal 0/150	` ,	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
#Uterus: Polyp Stromal					
Overall Incidence	To	0/50 otal 1/150	0 (0%) (0.67%)	0/50 (0%) Mean 0.67%	1/50 (2%) SD 1.15%
#Uterus: Sarcoma Stromal		- /			
Overall Incidence		0/50 otal 0/150	(0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
#Uterus: Sarcoma Stromal or Polyp Stromal					
Overall Incidence	То	0/50 otal 1/150	(0%) (0.67%)	0/50 (0%) Mean 0.67%	1/50 (2%) SD 1.15%
#Uterus: Schwannoma Malignant					
Overall Incidence	To	0/50 otal 0/150	` ,	0/50 (0%) Mean 0%	0/50 (0%) SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

Contract/Lab: All Laboratories

Toxicology Data Management System

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Report Date:04/29/2009

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: WATER

Length of Study: CHRONIC

		Male				Female			
#Vagina: Squamous Cell Carcinoma						0/50 (0%)	0/50 (0%)	0/50 (0%)	
Overall Incidence					Total	0/150 (0%)	Mean 0%	SD 0%	
#Vagina: Squamous Cell Papilloma				•••••				(201)	
Overall Incidence					Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	
#Zymbal's Gland: Carcinoma									
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	
Zymbal's Gland: Carcinoma or Adenoma	•••••								
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	

^{*:} Denominator is number of animals with tissues examined microscopically #: Denominator is number of animals necropsied